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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,413	03/30/2001	Shigeru Yamamoto	Q63731	8678

7590 12/10/2004
Sughrue Mion Zinn
Macpeak & Seas
2100 Pennsylvania Avenue NW
Washington, DC 20037

EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,413

Applicant(s)

YAMAMOTO ET AL.

Examiner

David J Steadman

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,11,13,14,22,24 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 and 22 is/are allowed.
- 6) ☒ Claim(s) 1,2,11,13,14,24 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Status of the Application

- [1] Claims 1-2, 4, 11, 13-14, 22, 24, and 26 are pending in the application.
- [2] Applicants' amendment to the claims, filed November 19, 2004, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [3] Applicants' amendment to the specification, filed November 19, 2004, is acknowledged.
- [4] Applicants' arguments filed November 19, 2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [5] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, Second Paragraph

- [6] Claims 24 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is necessitated by amendment.

Claims 24 and 26 recite *Rhizopus oryzae*, *Talaromyces emersonii*, *Mortierella vinacea*, *Cryptococcus albidus*, *Microbacterium arborescens*, and *Actinoplanes missouriensis*. There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 112, First Paragraph

[7] The new matter rejection of claims 1-2, 11, 13-14, 24, and 26 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth at item [7] of the Office action mailed August 19, 2004 and for the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue claims 1 and 11 have been amended to recite hybridization conditions that are disclosed at page 70 of the specification. Applicants' argument is not found persuasive.

While support for the hybridization conditions of "5X SSC, 1% blocking agent, 0.1% N-lauroylsarcosine sodium, 0.02% SDS, 68°C, overnight" (page 70, top) is apparent, the examiner can find no disclosure of the hybridization conditions as recited in claims 1 and 11 at page 70 of the instant specification. As such, the hybridization conditions recited in claims 1 and 11 are new matter as these hybridization conditions are not supported by the specification, claims, and/or drawings as originally filed.

[8] Claims 1-2, 11, 13-14, 24, and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is necessitated by amendment.

Claims 1 (claims 2 and 24 dependent therefrom) and 11 (claims 13-14 and 26 dependent therefrom) are drawn to a genus of polypeptides that are "naturally-

occurring." The specification discloses only a single representative species of such polypeptides, *i.e.*, SEQ ID NO:8. MPEP § 2163 states (citing *Amgen*, 927 F.2d at 1206, 18 USPQ2d at 1021), "A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials." In this case, the specification fails to define or describe those characteristics that distinguish a "naturally occurring" polypeptide having the recited characteristics from those polypeptides that also have the recited characteristics, but are not "naturally occurring." In other words, the specification fails to convey the common structural characteristics of the single disclosed species of SEQ ID NO:8 such that one can visualize the members of the genus and distinguish a subgenus of "naturally-occurring" polypeptides having the characteristics recited in claims 1 and 11 from the broader genus of naturally-occurring and non-naturally-occurring polypeptides having the recited characteristics. As such, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

Conclusion

[9] Status of the claims:

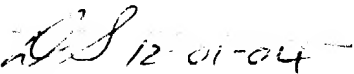
- Claims 1-2, 4, 11, 13-14, 22, 24, and 26 are pending.
- Claims 4 and 22 appear to be in a condition for allowance.
- Claims 1-2, 11, 13-14, 24, and 26 are rejected.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday from 7:30 am to 4:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 872-9306. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.


David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1652